

Richard Wolf Medical Instruments Corporation

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**510(k) Summary of Safety and Effectiveness**

<b>Submitter:</b>		<b>Date of Preparation:</b> January 10, 1997	
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Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			
<b>Product Information:</b>			
Trade name: RIWO CUT-Morcellator		Model number: 8386.205, 8385.181	
Common name: Tissue Morcellator		Classification name: Gynecologic laparoscope and accessories	
<b>Information on devices to which substantial equivalence is claimed:</b>			
510(k) Number	Trade or proprietary or model name	Manufacturer	
1 pre-enact.	1 Palmer grasping and biopsy forceps 8383.16	1 Richard Wolf	
2	2 Serrated Edged Macro-Morcellator-Set 15/5, type-no. 7674-1	2 Wisap	
3	3 STEINER Electromechanic Morcellator, type-no. 26712811	3 Karl Storz	
4 K942201	4 Trocar Sleeve System	4 Richard Wolf	

**1.0 Description**

The RIWO CUT-Morcellator 8386.205 is a manually operated rotary knife with a sealed protective sleeve. Via the protective sleeve, a grasping forceps 8385.181 for grasping the tissue to be morcellated is introduced also under gas-tight conditions. In the case of proper use (operating instructions), the replaceable cutting knife can not be damaged. The preassembled unit (consisting of Cutting Sleeve, protection sleeve and grasping forceps) is inserted into the trocar sleeve 8943.011, which was previously inserted into the abdominal wall with the help of the dilator and guide sleeve 8943.911.

**2.0 Intended Use**

**RIWO CUT-Morcellator 8386.205:**

The RIWO CUT-Morcellator is used in gynecologic and surgical laparoscopic procedures to shred large pieces of tissue and to remove myomata or other tissue by means of a manually operated tubular knife.

Severed tissue like myoma, uterus or cysts can be grasped by a forceps, morcellated, and extracted.



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The Trocar Sleeve, 8943.011 (internal diameter of 15mm) may be used for insertion of morcellator.

The Claw Grasping Forceps, 8385.181 can be used for grasping the tissue.

#### Claw Grasping Forceps 8385.181:

- The claw grasping forceps is used to grasp and hold organs and tissue (e.g. myomas) under laparoscopic view.
- The forceps can be inserted into the abdomen via a 10 mm trocar sleeve.
- The forceps can also be introduced via a 15/10 or 20/10 reducing sleeve with the corresponding trocar sleeves.
- The forceps can be used in connection with the RIWO CUT-Morcellator 8386.205.

#### Contraindications:

Observe contraindications for the patient which result from the general findings and are described in the relevant literature, for example:

- Use of a tissue bag for malignant or suspected malignant tissue.
- Do not use in vascularized tissue, devascularize first.
- Not for use as a dissecting tool.
- Potential damage to healthy tissue with inappropriate contact.
- User of instruments does not have appropriate training.

### 3.0 Technological Characteristics

**RIWO CUT-Morcellator:** A hardened knife with corrugated edge is screwed on the outer sleeve with 15 mm diameter. Via a handle provided with recessed grips, the cutting sleeve is made rotate by hand. The handle is fitted with a replaceable sealing system. The protective sleeve also provided with a sealing cap is introduced via the cutting sleeve. A claw grasping forceps (opening with both jaws) can be brought to the operation field via the protective sleeve. If the tissue to be morcellated is grasped with the grasping forceps, the forceps must be withdrawn into the protective sleeve until the marking is visible. This will ensure that the sharp cutting edges of the knife are not damaged by the forceps branches.

The claw grasping forceps is a tube shaft instrument with axial handle and spring-mechanism. The jaws have sharp hooks which enter into the tissue.

The trocar sleeve is a tube with a trumpet valve which can be opened, when the morcellator is inserted. The dilation and guide sleeve is a tube with a screw-in tip.

### 4.0 Substantial Equivalence

These devices are substantially equivalent to existing pre-enactment devices and 510(k) devices sold by Richard Wolf and 510(k) devices sold by Karl Storz and Wisap.

### 5.0 Performance Data

- A 100% outgoing test ensures, that there is no permanently deformation of the forceps if normally used.
- The steam sterilization tests performed by Richard Wolf shows, that the steam sterilization has no influence to the functional performance of the RIWO CUT-Morcellator or of the claw grasping forceps, when using the fractional method.

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**6.0 Clinical Tests**

No clinical tests performed.

**7.0 Conclusions Drawn**

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instructions manual.

By: Robert L. Casarsa  
Robert L. Casarsa  
Quality Assurance Manager

Date: \_\_\_\_\_

